K011957

JUL 1 8 2001

510(k) Summary

iVent™ 201 Portable Ventilator

with Remote Alarm Adapter

510(k) Number K011957

510(K) SUMMARY

A 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990. This 510(k) Summary meets the requirements identified in 21 C.F.R. §807.92.

Submitter's Name:

VersaMed Ltd..
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Contact Person:

Ken Raichman
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Trade Name:

iVent™ 201 Portable Ventilator

Classification Name:

Continuous Ventilator

Classification:

The FDA has classified these devices as a class II device (product code 73 CBK) and are reviewed by the Anesthesiology, Respiratory, and Defibrillator Devices Group.

Predicate Devices:

The ***iVent™ 201 Portable Ventilator with Remote Alarm adapter*** is substantially equivalent to the ***iVent™ 201 Portable Ventilator K981668***

Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the ***iVent™ 201 Portable Ventilator*** complies with the following voluntary standards: ASTM F1100-90, ASTM F1246-91, MIL-STD-810E, ISO 10651-1, ISO 10651-2, ISO 10651-3, EN 60601-1, EN 60601-1-2.

Indication for Use:

The ***iVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

- Assist/Control (Pressure Controlled or Volume Controlled)
- SIMV (Pressure Controlled or Volume Controlled)
- CPAP/PSV

The ***iVent™ 201*** ventilator is suitable for inter-hospital use, home and alternate-site use, transport and emergency use.

The ***iVent™ 201*** ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician and within the technical specification limits.

Intended Use of the *Alarm Adapter*: The Remote Alarm adapter is a device designed to connect the iVent 201 to a Central or Remote Alarm unit, such as a LIFECARE Remote Alarm Unit or similar device, for registration of the iVent 201 alarm output by a Central or Remote Alarm System.

Device Description:

The ***iVent™ 201*** is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. The ventilator is designed to treat a variety of clinical conditions. It can deliver oxygen-enriched air and may be used to administer nebulized medications by inhalation. The ***iVent™ 201*** can use external AC or DC power supply and contains an internal battery. Its operation is controlled by the ***iVent™ 201 Software.***

Description of Remote Alarm Adapter: The adapter connects between a Remote Alarm outlet on the iVent 201 Ventilator and the Central or Remote Alarm unit of the Hospital. The Adapter consists of a relay circuit, which meets the activating requirements of the Central or Remote Alarm unit. The iVent 201 with Remote Alarm Adapter will activate the Central or Remote Alarm unit for any major or medium priority alarm event that occurs on the iVent201.

Substantial Equivalence:

Based on a series of safety and performance testing we believe that the ***iVent™ 201*** with Remote Alarm Adapter is substantially equivalent to its predicate devices cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

Mr. Ken Raichman
VersaMed Ltd.
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Re: K011957
IVent™ 201 Portable Ventilator
Regulation Number: 868.5895
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: June 19, 2001
Received: June 22, 2001

Dear Mr. Raichman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 8

INDICATIONS FOR USE

510(k) Number (if known): K011957

Device Name: *iVent™ 201 Portable Ventilator (formally SmartVent 201)*

Indications for Use:

The *iVent™ 201* is a portable, computer controlled, electrically powered ventilator intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 10 kg (22 lb.), who require the following general modes of ventilatory support, as prescribed by an attending physician:

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(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Cardiovascular, Respiratory, and Neurological Devices

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Prescription Use _____ OR Over the Counter Use_____
(Per 21 CFR 801.109)